40 CFR Part 799

[OPTS-52098; FRL-3358-4]

Testing Consent Order on Methyl Tert-Butyl Ether and Response to the Interagency Testing Committee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document announces that EPA has signed an enforceable Testing Consent Order for methyl tert-butyl ether (MTBE) with five manufacturers of the MTBE Health Effects Testing Task Force. These manufacturers have agreed to perform certain health effects tests on MTBE. This rule adds MTBE to the list of Testing Consent Orders in 40 CFR 799.5000 for which the export notification requirements of 40 CFR Part 707 apply. This document constitutes EPA's response to the Interagency Testing Committee's (ITC) recommendation that EPA consider health effects and chemical fate testing of MTBE.

EFFECTIVE DATE: March 31, 1988.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Acting Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M Street SW., Washington, DC 20460, (202) 554-1404.

SUPPLEMENTARY INFORMATION: Under procedures described in 40 CFR Part 790, five manufacturers have entered into a Testing Consent Order with EPA in which these five manufacturers have agreed to perform certain health effects testing of MTBE. This rule amends 40 CFR 799.5000 to add MTBE to the list of chemical substances and mixtures subject to Testing Consent Orders.

I. ITC Recommendations

In its 19th report to EPA, published in the **Federal Register** of November 14, 1986 (51 FR 41417), the ITC recommended with intent to designate that MTBE (also identified as 2-methoxy-2-methyl propane) (CAS No. 1634-04-4) be considered for health effects and chemical fate testing. In the ITC's 20th Report to EPA, published in the **Federal Register** of May 20, 1987 (52 FR 19020), MTBE was designated for response within 12 months. The ITC designated MTBE based on concerns of widespread human exposure to low-level fugitive emissions of MTBE at gasoline pumps and the lack of chronic health effects information. The health effects test recommended by the ITC was a chronic inhalation toxicity test including neurotoxic, hematologic, and oncogenic effects. The chemical fate test recommended was a monitoring study to determine typical concentrations of MTBE vapor at representative gasoline terminals and service stations.

II. Testing Consent Order Negotiations

Previous to the publication of "Procedures Governing Testing Consent Agreements and Test Rules Under the Toxic Substances Control Act" (51 FR 23706) on June 30, 1986, EPA made findings under TSCA section 4 as the basis for rulemaking in response to the ITC's designation of chemical substances for priority testing. A finding was made under either section 4(a)(1)(A) (with evidence of unreasonable risk of injury to health or to the environment) or section 4(a)(1)(B) (with evidence of substantial quantities being produced and significant or substantial exposure to health or the environment). EPA has amended the regulations for rulemaking to expedite the development of data for risk assessment by establishing the TSCA section 4 testing consent order process. The Consent Order is not based on a formal finding and expedites testing while retaining the same TSCA penalty provisions applicable under rulemaking.

In accordance with the procedures in 40 CFR 790.22, EPA held a public "focus meeting" on December 17, 1986, to discuss the ITC's testing recommendations for MTBE and to obtain comments. On February 3, 1987, a notice soliciting interested parties for the consent order negotiations was published in the **Federal Register** (52 FR 3343). The MTBE Health Effects Testing Task Force (MTBE Task Force) presented its review of chemical fate and health effects data at a public meeting on March 5, 1987. EPA's tentative testing decisions were presented in a public meeting on April 21, 1987.

Negotiations on a Testing Consent Order (Order) were initiated at a May 8, 1987, public meeting when producers of MTBE, represented by the MTBE Task

Force under the Oxygenated Fuels Association Inc., outlined their proposed testing program. The MTBE Task Force also listed items for discussion with the Agency. Subsequently, negotiation meetings were held on May 19 and July 14, 1987, to discuss the draft order. A comment resolution meeting was held October 1, 1987, to resolve questions on test protocols in the draft. On January 22, 1988, five MTBE manufacturers: Amoco Corporation; ARCO Chemical Company; Exxon Chemical Company, a Division of Exxon Corporation; Sun Refining and Marketing Company; and Texaco Chemical Company signed a Testing Consent Order with EPA. Under this Order the principal test sponsors agreed to conduct or provide for the conduct of the following health effects tests: An *in vivo* mammalian bone marrow cytogenetics test; a sex-linked recessive lethal assay in *Drosophila melanogaster;* a rodent dominant lethal assay; pharmacokinetics tests to relate oral, dermal, and inhalation routes of exposure; a 90-day inhalation subchronic test including: Neuropathology, motor activity and the functional observational battery tests; and inhalation developmental toxicity study in two species; and inhalation oncogenicity test in two species; and an inhalation two-generation reproduction and fertility effects study. The specific test standards to be followed and the testing schedule for each test are included in the Order. It is EPA's determination that this testing battery is more than adequate to evaluate MTBE for the effects identified by the ITC. Procedures for submitting study plans, modifying the Order, monitoring the testing and other provisions are also included in the Order as specified in 40 CFR 790.60.

III. Use and exposure

MTBE is a clear liquid with a vapor pressure of 245 mm/Hg at 25° C. MTBE is used almost exclusively as a blending component in high octane gasoline. Typical concentrations of MTBE in gasoline range from 2 to 8 percent by volume. EPA has approved up to 11 percent MTBE by volume (45 FR 67443; October 10, 1980). An estimated 3 to 13 percent of the gasoline sold in 1985, about 3 to 13 billion gallons, contained MTBE (Ref. 1).

Annual plant capacity of MTBE production was estimated at about 4 billion pounds in 1986. The growth rate in production of MTBE was estimated to be 19 percent per year from 1985 to 1990. However, between 1982 and 1985, production increased over 140 percent (Ref. 1).

The 1980 National Occupational Exposure Survey estimated 2,571 workers were exposed to MTBE in the work place (Ref. 2). This estimate only included: Life scientists, clinical laboratory technicians, and production testers. The life scientist and laboratory technician exposures would probably occur as a result of the relatively small amount of MTBE used in procedures to dissolve cholesterol gallstones and to extract metabolic organic acids. EPA estimates that as many as 35,000 more workers may be exposed during bulk loading, unloading, and shipment of MTBE-containing gasoline (Ref. 3). Gas station attendants and consumers who pump their own gasoline would also be exposed to MTBE vapor from MTBE-containing gasoline (Refs. 5 and 9).

Although the Occupational Safety and Health Administration (OSHA) has not established any standards for exposure to gasoline or MTBE, the American Conference of Governmental Industrial Hygienists (ACGIH) has established a Threshold Limit Value of 300 ppm (900 mg/m³) for gasoline (Ref. 3). Sun Refining and Marketing Company recommends an 8-hour time weighted average (TWA) exposure limit of 100 ppm (300 mg/m³) for MTBE (Ref. 10). However, Texaco Chemical Company recommends a limit of 200 ppm (600 mg/m³) for MTBE (Ref. 11).

Worker exposure to MTBE vapor measured in refineries has been generally less than 1 ppm (3 mg/m³) for an 8-hour TWA. The highest exposure level to MTBE vapor reported was a TWA of 33 ppm (100 mg/m³) and a short-term exposure of 45 ppm (135 mg/m³) (Ref. 4). Approximately 50 percent of the MTBE produced is shipped off-site before blending (Ref. 3). Short-term exposure to MTBE vapor during bulk loading and unloading operations has been estimated to be as high as 550 ppm (1,650 mg/m³) (Ref. 3). However, such high exposure could be decreased if engineering controls are used in the loading operations. No data were available from industry for MTBE vapor exposure during the loading, unloading, or shipping of MTBE.

Exposure to MTBE vapor during transfer of MTBE-containing gasoline has been estimated from gasoline vapor measurements, assuming 7 percent MTBE concentration by volume. During bulk loading and delivery of MTBE-containing gasoline, exposure to MTBE vapor was estimated to be short-term exposure of 8 ppm (23 mg/m³) for the truck drivers 98 percent of the time (Refs. 1 and 3). Service station attendants' exposure to MTBE vapor has been estimated to be as high as 8.6 ppm (31 mg/m³) for an 8-hour TWA (Ref. 1). Total MTBE vapor release can be calculated from volatile organic carbon (VOC) emissions estimated for gasoline (52 FR 31162; August 19, 1987). Assuming MTBE accounts for 8 to 11 percent of total VOC emissions from gasoline, MTBE vapor release would be 3 to 17 million kg/yr (Ref. 5).

MTBE vapor exposure *via* gasoline was the major concern expressed in the 19th ITC report. However EPA has an additional concern about MTBE contamination of ground water. Although only a few cases of ground water contamination are currently documented, the rapid growth in production, transport, and use of MTBE will probably contribute to an increase in incidents of contamination. The relatively recent appearance of MTBE in the market place has hampered the documentation of ground water contamination because laboratory analyses do not typically screen for this compound and gasoline is composed of more than 50 different hydrocarbon compounds (Ref. 9). MTBE is relatively water soluble (40,000 to 51,260 mg/L) compared to other gasoline components (Ref. 1). This solubility, coupled with the fact that an estimated 35 percent of the approximately 638,000 non-farm underground motor fuel tanks would not pass the EPA tightness test, indicates the potential ground water contamination problem (Ref. 1).

The largest identified population affected by MTBE-contaminated water was Rockaway Township in New Jersey, population 20,000 (Ref. 6). The level of MTBE contamination in the township wells ranged from 25 to 40 ppb and required aeration treatment before delivery to the township's residents. EPA has received requests for information on MTBE as a result of other well water contamination reports in New Jersey and New Hampshire (Ref. 7). A leaking underground storage tank in a rural area of Maine has contaminated household wells in the vicinity with MTBE concentrations as high as 690 ppb (Ref. 8). Maine and New Jersey have set a maximum contaminant level of 50 ppb for MTBE (Refs. 6 and 8).

IV. Testing Program

A. Chemical Fate

In the ITC's 19th Report to EPA (51 FR 41417), the ITC recommended that monitoring studies be conducted at sites where MTBE-containing gasoline is transferred. In comments submitted at the Focus Meeting, industry representatives claimed that worst-case exposures to MTBE from gasoline

vapors can be accurately calculated from existing data. As indicated in Unit II, exposure to MTBE vapor can be estimated from measurements of gasoline vapor and the proportion of MTBE in the gasoline mixture (Ref. 5). On August 19, 1987, EPA proposed systems to limit gasoline vapor emissions during refueling (52 FR 31162) and evaporative emissions (52 FR 31274). The implementation of these regulations would decrease levels of consumer exposure to MTBE vapors in service stations. Promulgation of these regulations is expected in 1989.

The Agency concluded that MTBE exposure in service stations can be estimated from existing data. The number of parameters affecting a vapor monitoring study would probably yield highly variable results. It would be difficult to obtain nationally representative data. Currently the Agency believes that it can reasonably rely on models to conservatively estimate worker exposure as presented in Unit III (Ref. 3). However, changes in gasoline fuel composition in the future may require a re-evaluation of this estimate.

B. Health Effects

The 19th ITC Report recommended a chronic inhalation toxicity test including neurotoxic, hematologic and oncogenic effects. In response to the TSCA section 8(d) Health and Safety Data Reporting Rule for MTBE, triggered by the ITC recommendation, the following studies were submitted to EPA: two inhalation developmental toxicity studies (one in rats and one in mice); and inhalation single generation reproduction/fertility study in rats; acute toxicity data; gene mutation and chromosomal aberration studies; two 90-day inhalation toxicity studies; and a dermal sensitization study. Several studies were submitted which used gasoline mixtures containing different amounts of MTBE.

The Agency has reviewed these studies and determined that additional testing is necessary to determine whether the distribution and use of MTBE presents an unreasonable risk of injury to health. As discussed above, producers of MTBE, represented by the MTBE Task Force, have agreed to perform the necessary tests to determine the effects, if any, associated with the use and distribution of MTBE (see Unit II).

The testing conducted under this Order will be used by EPA to determine the risk of adverse health effects associated with the use and distribution of MTBE.

V. Export Notification

The issuance of this Testing Consent Order subjects any person who exports or intends to export MTBE to the export notification requirements of section 12(b) of TSCA. The specific requirements are listed in 40 CFR Part 707. In the June 30, 1986, Interim Final Rule (51 FR 23706) establishing the Testing Consent Order process, EPA added and reserved Subpart C of Part 799 for a listing of testing consent orders issued by EPA. This listing serves as notification to persons who export or who intend to export chemical substances or mixtures which are the subject of testing consent orders that 40 CFR Part 707 applies.

VI. Rulemaking Record

EPA has established a record for this rule (docket number OPTS-42098). This record contains the basic information considered by the Agency in developing this rule.

A. Supporting Documentation

(1) Testing Consent Order for Methyl tert-Butyl Ether.

(2) **Federal Register** notices pertaining to this rule consisting of:

(a) Notice containing the ITC recommendation with intent-to-designate MTBE (51 FR 41417; November 14, 1986).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on MTBE (51 FR 41328; November 14, 1986).

(c) Notice soliciting interested parties for developing a Testing Consent Order for MTBE (52 FR 3343; February 3, 1987).

(d) Notice containing the ITC designation of MTBE for response within 12 months (52 FR 19020; May 20, 1987).

(e) Notice of procedures governing testing consent agreements and test rules under the Toxic Substances Control Act (51 FR 23706; June 30, 1986).

(f) Notice proposing refueling emission regulations for gasoline fueled light-duty vehicles and trucks and heavy-duty vehicles (52 FR 31162; August 19, 1987).

(g) Notice proposing volatility regulations for gasoline and alcohol blends sold in 1989 and later calendar years and control of air pollution from new motor vehicles and new motor vehicle engines: evaporative emissions regulations for 1990 and later model year gasoline-fueled light-duty vehicles, light-duty trucks and heavy-duty vehicles (52 FR 31274; August 19, 1987).

(h) Notice on fuels and fuel additives: definition of substantially similar (45 FR 67443; October 10, 1980).

(3) Comunications consisting of:

(a) Written letters

(b) Contact reports of telephone conversations

(c) Meeting summaries

(4) Reports—published and unpublished materials.

B. References

(1) Neal, M.W., Anatra, M., Jacobson, R.A. *et al.* Draft Final Technical Support Document Methyl tert-Butyl Ether. Contract No. 68-02-4209. Prepared by Syracuse Research Corporation, Syracuse, New York for the Environmental Protection Agency, Office of Toxic Substances, Washington, DC. (February 26, 1987).

(2) National Occupational Exposure Survey (1980 to 1983). Department of Health and Human Services, National Institute for Occupational Safety and Health, Cincinnati, OH. (1984).

(3) U.S. Environmental Protection Agency (USEPA). Worker Exposure Assessment of Methyl tert-Butyl Ether. Environmental Protection Agency, Chemical Engineering Branch, Office of Toxic Substances, Washington, DC. (May 7, 1987).

(4) Texaco Chemical Company. TSCA section 8(d) submission 86-870000242. Memorandum from R.T. Richards to: F.E. Bentley, R.J. Breglia, R.A. Cox, *et al.* (November 24, 1986).

(5) Furey, R.L., and King, J.B. "Evaporative and exhaust emissions from cars fueled with gasoline containing ethanol or methyl tert-butyl ether". Society of Automotive Engineers, Inc. Paper 800261 presented at the International Congress and Exposition, Detroit, Michigan. (February, 1980).

(6) McKinnon, R.J., and Dyksen, J.E. "Removing organics from ground water through aeration plus GAC." *Journal of the American Water Works Association* 76:42-47. (1984).

(7) USEPA. Memorandum from F.D. Kover to M.B. Cooke and M. Mlay. (May 23, 1986).

(8) Garrett, P., Moreau, M., and Lowry, J.D. "Methyl tertiary butyl ether as a ground water contaminant". Proceedings of Petroleum Hydrocarbons and Organic Chemicals in Ground Water Conference. NWWA-API pg. 227-238. (November 1986).

(9) Tironi, G., Nebel, G.J., and Williams, R.L. "Measurement of vapor exposure during gasoline refueling". Society of Automotive Engineers, Inc. Paper 860087 presented at the International Congress and Exposition, Detroit, Michigan. (February, 1986).

(10) Sun Refining and Marketing Company, Philadelphia, PA 19102. Letter from Brian C. Davis to Beth Anderson, Environmental Protection Agency, Office of Toxic Substances, Washington, DC. (February 10, 1987).

(11) Texaco Chemical Company. TSCA section 8(d) submission 86-870000239.

Memorandum from J.E. Wiki to M.M. Simer (November 13, 1986).

Confidential Business Information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OTS Public

Information Office, Rm. NE-G004, 401 M Street SW., Washington, DC from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

List of Subjects in 40 CFR Part 799

Testing procedures, Environmental protection, Hazardous substances, Chemicals, Chemical export, Recordkeeping and reporting requirements.

Dated: March 16, 1988.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by revising the table to read as follows:

§ 799.5000 Testing consent orders.

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CAS Number	Substance or mixture name	Testing	FR citation
328-84-7	3,4-Dichlorobenzotrifluoride	Environmental effects	June 23, 1987
		Chemical fate	June 23, 1987
1634-04-4	Methyl tert-butyl ether	Health effects	March 31, 1988.

[FR Doc. 88-7063 Filed 3-30-88; 8:45 am]

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